Application No.: 09/391,606

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REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of two months of the period for response to the Office Action. Our cheque in respect of the prescribed fee is enclosed.

The Examiner maintained rejection of claims 10 and 11 under 35 USC 112, second paragraph, as being indefinite. The Examiner suggested use of the expression the 76 kDa protein. Claims 10 and 11 have been amended in accordance with the Examiner's suggestion.

It is submitted that claims 10 and 11 can no longer be considered indefinite in this respect.

The Examiner maintained rejection of claims 1, 2, 4 to 7, 9 to 17, 19 and 20 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the invention, at the time the application was filed, had possession of the claimed invention.

In this regard, the Examiner had previously noted that the specification only discloses nucleotide sequences encoding MOMP (SEQ ID No: 11) or 76 kDa protein (SEQ ID No: 12) of a strain of *C. pneumoniae* and fails to provide the nucleotide sequences encoding the MOMP or 76 kDa protein derived from various species and strains of *Chlamydia*.

As noted previously, the specification is addressed to a person skilled in the art. It is not necessary for the specification to teach a person skilled in the art what he already knows. The invention is directed to an immunogenic composition comprising two specific materials, one containing a nucleotide sequence encoding a major outer membrane protein (MOMP) of a strain of *Chlamydia* and the other containing a nucleotide sequence encoding a 76 kDa protein of a strain of *Chlamydia*.

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The proteins are known proteins and their sequences and encoding nucleotide sequences have been published prior to the filing of this application and those skilled in the art have this information. To the extent those skilled in the art possess this publicably-available information, the applicants also were in possession of this information at the time of filing of this application.

Accordingly, the rejection of claims 1, 2, 4 to 7, 9 to 17, 19 and 20 under 35 USC 112, first paragraph, on this ground, should be withdrawn.

The Examiner rejected claims 1, 2, 4-to 7 and 9-to 20 under-35 USC 112, first paragraph, on the basis that the specification, which being enabling for administration of a plasmid encoding the disclosed MOMP and a plasmid encoding the disclosed 76 kDa of *C. pneumoniae* before challenge by *C. pneumoniae* and induction of a protective immune response against sublethal *C. pneumoniae* lung infection in mice, does not reasonably provide enablement for an immunogenic composition comprising a vector encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for the protection of any host, including human, against a particular disease, such as any chlamydial infection.

With respect to the MOMP and/or 76 kDa protein, the Examiner's attention is directed to the preceding discussion. The specific vectors used are but examples of the invention defined in claim 1, which is directed to an immunogenic composition.

The vectors are used to provide protection against *C. pneumoniae* lung infection in mice. As the Examiner will appreciate, the mouse is the animal model of choice for chlamydial infection in humans.

Contrary to the Examiner's view, the claims do <u>not</u> read on gene therapy *in vivo*. The claims are directed to an immunogenic composition and not to a method of administration. The <u>use</u> to which the immunogenic composition is put is Irrelevant.

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In any event, it is evident that the composition is used to protect against chlamydial infection. The Examiner's reference to cell proliferation is not understood. The Examiner points to no prior art which suggests that chlamydial antigens may be used to protect against infections other than chlamydial infections.

Having regard to the above, it is submitted that claims 1, 2, 4 to 7 and 9 to 20 are fully enabled and are no longer open to rejection under 35 USC 112, first paragraph, on this ground.

Entry of this amendment after Final Action is requested, in that the application thereby is placed in condition for allowance. In the event the Examiner considers one or more ground of rejection to apply, the Amendment nevertheless should be entered, since the claims thereby are placed in better condition for appeal and/or issues for appeal are reduced.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,

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Toronto, Ontario, Canada, (416) 595-1155 FAX No. (416) 595-1163 Date: March 26, 2003

Applicant: Andrew D. Murdin Application No.: 09/391,606

Title: IMMUNOGENIC COMPOSITIONS FOR PROTECTION AGAI

CHLAMYDIAL INFECTION

New Appln, Cheque, Formal Papers: ()
Retyped Required in Notice of Allowance: ()

Final Fee: ()

Other: Amendment after Final Action, Extension of Time Request and Chegne (4)

Due Date: March 31, 2003

Please place the official stamp of the Patent Office on this card and return it to us for our files to constitute an acknowledgment by the Patent Office of receipt of the above-identified papers on the date stamped.

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